

- d) an interpolation formula to calculate the insulin action value  $F_k(t_d)$  programmed into the processor, the formula to calculate the insulin action value comprising:

$$F_k(t_d) = Y_0 + ((Z_k - X_0)(Y_1 - Y_0)/(X_1 - X_0))$$

wherein  $X_0$  represents an initial insulin dose,  $Y_0$  represents an insulin action value at initial dose  $X_0$ ,  $X_1$  represents a following insulin dose,  $Y_1$  represents an insulin action value at following insulin dose  $X_1$ , and  $Z_k$  represents time after injection of insulin dose  $I_k$  at time  $t_d$ ;

- e) a formula to calculate the future blood glucose value  $G(t_j)$  programmed into the processor, the formula to calculate the food glucose value comprising:

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$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k F_k(t_d) - F_k(t_j) \right]$$

wherein  $S$  represents insulin sensitivity values,  $I_k$  represents insulin dose values administered prior to time  $t_d$ , and  $F_k(t_j)$  represents insulin action values at time  $(t_j)$ ,  $k=1$  represents a single insulin bolus dose and a supplemental insulin bolus dose, and  $N$  represents the total number of insulin bolus doses and supplemental insulin bolus doses; and

- f) a display means connected to said processor for displaying said future blood glucose value  $G(t_j)$ , thereby enabling the patient to take timely corrective action to prevent hypoglycemia or hyperglycemia.

52<sup>2</sup>. The apparatus of Claim 51<sup>1</sup>, wherein said memory means includes means for storing maximum and minimum values defining a target blood glucose range of the patient, said processor includes means for determining if said future blood glucose value  $G(t_j)$  lies outside of said target range and means for determining said corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range, and said display means includes means for recommending said corrective action to the patient.

53<sup>3</sup>. The apparatus of Claim 52<sup>2</sup>, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises an administration of a supplemental insulin dose, and said processor further comprises means for

determining said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

54. The apparatus of Claim 52, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises a consumption of a number of grams of carbohydrates, and said processor further comprises means for determining said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

55. The apparatus of Claim 51, wherein said memory means further includes means for storing a hypoglycemic value indicative of a hypoglycemic threshold of the patient, said processor includes means for determining if said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value, and said apparatus further comprises audio means connected to aid processor for audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

56. The apparatus of Claim 51, wherein said input means comprises a blood glucose measuring means for measuring a blood sample of the patient and for producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

57. The apparatus of Claim 51, wherein said insulin dose has an insulin type, said input means includes means for entering said insulin type, and said processor includes means for determining said insulin action value  $F_k(t_d)$  in dependence upon said insulin type.

58. The apparatus of Claim 57, wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.

59. The apparatus of Claim 51, wherein said processor includes means for determining an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose and means for determining said future blood glucose  $G(t_j)$  in further dependence upon said insulin action value  $F_k(t_j)$ .

60. The apparatus of Claim 51, wherein said processor includes means for determining an ultimate time point at which said insulin dose will have no insulin action remaining and means for setting time  $t_j$  equal to said ultimate time point.

61. The apparatus of Claim 51, wherein said processor includes means for determining a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient, and wherein said display means includes means for displaying said future blood glucose values in graphical form.

62. The apparatus of Claim 51, further comprising a communication means connected to said processor for establishing a communication link between said apparatus and a healthcare provider computer and for transmitting and receiving data therebetween.

63. The apparatus of Claim 62, wherein said communication means comprises a modem means for establishing said communication link through a communication network.

64. The apparatus of Claim 62, wherein said communication means comprises an input/output port for establishing said communication link through a connection cord.

65. A system for assisting a patient having diabetes mellitus in controlling blood glucose, said system comprising:

- a) an input means for entering a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value  $I_k$  representative of an insulin dose administered to the patient prior to time  $t_d$ ;
- b) a memory means for storing maximum and minimum values defining a target blood glucose range of the patient, an insulin sensitivity value representative of an insulin sensitivity of the patient, and information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose;
- c) a processor connected to said input means and said memory means for determining said insulin action value  $F_k(t_d)$ , for determining a future blood glucose value  $G(t_j)$  representative of an expected blood glucose concentration of the patient at time  $t_j$ , and for determining a corrective action for the patient when

said future blood glucose value  $G(t_j)$  lies outside of said target range, wherein said processor determines said future blood glucose value  $G(t_j)$  in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ; and

- d) an interpolation formula to calculate the insulin action value  $F_k(t_d)$  programmed into the processor, the formula to calculate the insulin action value comprising:

$$F_k(t_d) = Y_0 + ((Z_k - X_0)(Y_1 - Y_0)/(X_1 - X_0))$$

wherein  $X_0$  represents an initial insulin dose,  $Y_0$  represents an insulin action value at initial dose  $X_0$ ,  $X_1$  represents a following insulin dose,  $Y_1$  represents an insulin action value at following insulin dose  $X_1$ , and  $Z_k$  represents time after injection of insulin dose  $I_k$  at time  $t_d$ ;

- e) a formula to calculate the future blood glucose value  $G(t_j)$  programmed into the processor, the formula to calculate the food glucose value comprising:

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$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k F_k(t_d) - F_k(t_j) \right]$$

wherein  $S$  represents insulin sensitivity values,  $I_k$  represents insulin dose values administered prior to time  $t_d$ , and  $F_k(t_j)$  represents insulin action values at time  $(t_j)$ ,  $k=1$  represents a single insulin bolus dose and a supplemental insulin bolus dose, and  $N$  represents the total number of insulin bolus doses and supplemental insulin bolus doses; and

- f) a display means connected to said processor for recommending said corrective action to the patient.

66. The system of Claim 65, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises an administration of a supplemental insulin dose, and said processor further comprises means for determining said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

67. The system of Claim 65, wherein said memory means further includes means for storing a target blood glucose value of the patient, said corrective action comprises a

consumption of a number of grams of carbohydrates, and said processor further comprises means for determining said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

68.<sup>18</sup> The system of Claim 65,<sup>15</sup> wherein said memory means further includes means for storing a hypoglycemic value indicative of a hypoglycemic threshold of the patient, said processor includes means for determining if said future blood glucose  $G(t_j)$  lies below said hypoglycemic value, and said system further comprises audio means connected to said processor for audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

69.<sup>19</sup> The system of Claim 65,<sup>15</sup> wherein said input means comprises a blood glucose measuring means for measuring a blood sample of the patient and for producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

70.<sup>20</sup> The system of Claim 65,<sup>15</sup> wherein said insulin dose has an insulin type, said input means includes means for entering said insulin type, and said processor includes means for determining said insulin action value  $F_k(t_d)$  in dependence upon said insulin type.

71.<sup>21</sup> The system of Claim 70,<sup>20</sup> wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.

72.<sup>22</sup> The system of Claim 65,<sup>15</sup> wherein said processor includes means for determining an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose and means for determining said future blood glucose value  $G(t_j)$  in further dependence upon said insulin action value  $F_k(t_j)$ .

73.<sup>23</sup> The system of Claim 65,<sup>15</sup> wherein said processor includes means for determining an ultimate time point at which said insulin dose will have no insulin action remaining and means for setting time  $t_j$  equal to said ultimate time point.

74.<sup>24</sup> The system of Claim 65,<sup>15</sup> wherein said processor includes means for determining a plurality of future blood glucose values representative of a corresponding plurality of expected

blood glucose concentrations of the patient, and wherein said display means includes means for displaying said future blood glucose values in graphical form.

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75. The system of Claim 65, wherein said input means includes means for entering a plurality of blood glucose values and a plurality of insulin dose values, and said system further comprises a computing means in communication with said processor for receiving said blood glucose values and said insulin dose values and for calculating from said blood glucose values and said insulin dose values an adjusted insulin sensitivity value.

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76. The system of Claim 75, wherein said input means, said memory means, said processor, and said display means are included in a patient-operated apparatus, said computing means comprises a healthcare provider computer, and said apparatus includes a communication means connected to said processor for establishing a communication link between said apparatus and said healthcare provider computer.

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77. The system of Claim 76, wherein said communication means comprises a modem means for establishing said communication link through a communication network.

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78. The system of Claim 76, wherein said communication means comprises an input/output port for establishing said communication link through a connection cord.

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79. A method for assisting a patient having diabetes mellitus in controlling blood glucose, said method comprising the following steps:

- a) providing the patient with an apparatus for determining a future blood glucose value  $G(t_f)$  representative of an expected blood glucose concentration of the patient at time  $t_f$ , wherein said apparatus comprises a memory, an input means for entering a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value representative of an insulin dose administered to the patient prior to time  $t_d$ , a display, and a processor connected to said memory, said input means, and said display;
- b) storing in said memory an insulin sensitivity value representative of an insulin sensitivity of the patient;

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- c) storing in said memory information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose;
- d) entering in said processor said insulin dose value and said blood glucose value  $G(t_d)$ ;
- e) determining in said processor said insulin action value  $F_k(t_d)$  by programming the processor to execute an interpolation formula to calculate the insulin action value  $F_k(t_d)$  programmed into the processor, the formula to calculate the insulin action value comprising:

$$F_k(t_d) = Y_0 + ((Z_k - X_0)(Y_1 - Y_0)/(X_1 - X_0))$$

wherein  $X_0$  represents an initial insulin dose,  $Y_0$  represents an insulin action value at initial dose  $X_0$ ,  $X_1$  represents a following insulin dose,  $Y_1$  represents an insulin action value at following insulin dose  $X_1$ , and  $Z_k$  represents time after injection of insulin dose  $I_k$  at time  $t_d$ ;

- f) determining in said processor said future blood glucose value  $G(t_j)$  in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$  by programming the processor to execute a formula to calculate the future blood glucose value  $G(t_j)$  programmed into the processor, the formula to calculate the food glucose value comprising:

$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k F_k(t_d) - F_k(t_j) \right]$$

wherein  $S$  represents insulin sensitivity values,  $I_k$  represents insulin dose values administered prior to time  $t_d$ , and  $F_k(t_j)$  represents insulin action values at time  $(t_j)$ ,  $k=1$  represents a single insulin bolus dose and a supplemental insulin bolus dose, and  $N$  represents the total number of insulin bolus doses and supplemental insulin bolus doses; and

- g) displaying said future blood glucose value  $G(t_j)$  on said display, thereby enabling the patient to take timely corrective action to prevent hypoglycemia or hyperglycemia.

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80. The method of Claim 79<sup>29</sup>, further comprising the step of determining in said processor an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose, and wherein said future blood glucose value  $G(t_j)$  is determined in further dependence upon said insulin action value  $F_k(t_j)$ .

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81. The method of Claim 79<sup>29</sup>, wherein the step of determining said future blood glucose value  $G(t_j)$  is preceded by the steps of determining in said processor an ultimate time point at which said insulin dose will have no insulin action remaining and setting time  $t_j$  equal to said ultimate time point.

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82. The method of Claim 79<sup>29</sup>, further comprising the steps of determining in said processor a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient and displaying said future blood glucose values in graphical form on said display.

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83. The method of Claim 79<sup>29</sup>, further comprising the steps of storing in said memory maximum and minimum values defining a target blood glucose range of the patient, determining in said processor if said future blood glucose value  $G(t_j)$  lies outside of said target range, determining in said processor said corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range, and recommending said corrective action on said display.

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84. The method of Claim 83<sup>33</sup>, wherein said corrective action comprises an administration of a supplemental insulin dose, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

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85. The method of Claim 83<sup>33</sup>, wherein said corrective action comprises a consumption of a number of grams of carbohydrates, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$

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86. The method of Claim 79<sup>29</sup>, further comprising the steps of storing in said memory a hypoglycemic value indicative of a hypoglycemic threshold of the patient, determining in said processor if said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value, and



audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

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37 87. The method of Claim 76, wherein said input means comprises a blood glucose meter and the step of entering said blood glucose value  $G(t_d)$  comprises the steps of measuring a blood sample of the patient with said glucose meter and producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

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38 88. The method of Claim 79, wherein said insulin dose has an insulin type, said method further comprises the step of entering said insulin type in said processor, and said insulin action value  $F_k(t_d)$  is determined in dependence upon said insulin type.

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39 89. The method of Claim 88, wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.

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90. A method for assisting a patient having diabetes mellitus in controlling blood glucose, said method comprising the following steps:

- a) providing the patient with an apparatus for determining a future blood glucose value  $G(t_j)$  representative of an expected blood glucose concentration of the patient at time  $t_j$ , wherein said apparatus comprises a memory, an input means for entering a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value representative of an insulin dose administered to the patient prior to time  $t_d$ , a display, and a processor connected to said memory, said input means, and said display;
- b) storing in said memory an insulin sensitivity value representative of an insulin sensitivity of the patient, information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose, and maximum and minimum values defining a target blood glucose range of the patient;
- c) entering in said processor said insulin dose value and said blood glucose value  $G(t_d)$ ;
- d) determining in said processor said insulin action value  $F_k(t_d)$  by programming the processor to execute an interpolation formula to calculate the insulin action value  $F_k(t_d)$  as stated in the formula to calculate the insulin action value comprising:

$$F_k(t_d) = Y_0 + ((Z_k - X_0)(Y_1 - Y_0)/(X_1 - X_0))$$

wherein  $X_0$  represents an initial insulin dose,  $Y_0$  represents an insulin action value at initial dose  $X_0$ ,  $X_1$  represents a following insulin dose,  $Y_1$  represents an insulin action value at following insulin dose  $X_1$ , and  $Z_k$  represents time after injection of insulin dose  $I_k$  at time  $t_d$ ;

- e) determining in said processor said future blood glucose value  $G(t_j)$  by programming the processor to execute a formula to calculate the future blood glucose value  $G(t_j)$  using the formula to calculate the food glucose value comprising:

$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k F_k(t_d) - F_k(t_j) \right]$$

wherein  $S$  represents insulin sensitivity values,  $I_k$  represents insulin dose values administered prior to time  $t_d$ , and  $F_k(t_j)$  represents insulin action values at time  $(t_j)$ ,  $k=1$  represents a single insulin bolus dose and a supplemental insulin bolus dose, and  $N$  represents the total number of insulin bolus doses and supplemental insulin bolus doses, and in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ;

- f) determining in said processor if said future blood glucose value  $G(t_j)$  lies outside of said target range;
- g) determining in said processor a corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range; and
- h) recommending said corrective action to the patient on said display.

91. The method of claim 90, further comprising the step of determining in said processor an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose, and wherein said future blood glucose value  $G(t_j)$  is determined in further dependence upon said insulin action value  $F_k(t_j)$ .

92. The method of Claim 90, wherein the step of determining said future blood glucose value  $G(t_j)$  is preceded by the steps of determining in said processor an ultimate time point at

which said insulin dose will have no insulin action remaining and setting time  $t_j$  equal to said ultimate time point.

93. The method of Claim 90, further comprising the steps of determining in said processor a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient and displaying said future blood glucose values in graphical form on said display.

94. The method of Claim 90, wherein said corrective action comprises an administration of a supplemental insulin dose, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said supplemental insulin dose in dependence upon said insulin sensitivity value and a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

95. The method of Claim 90, wherein said corrective action comprises a consumption of a number of grams of carbohydrates, and said method further comprises the steps of storing in said memory a target blood glucose value of the patient and determining in said processor said number of grams in dependence upon a difference between said future blood glucose value  $G(t_j)$  and said target blood glucose value.

96. The method of Claim 90, further comprising the steps of storing in said memory, a hypoglycemic value indicative of a hypoglycemic threshold of the patient, determining in said processor if said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value, and audibly alerting the patient when said future blood glucose value  $G(t_j)$  lies below said hypoglycemic value.

97. The method of Claim 90, wherein said input means comprises a blood glucose meter and the step of entering said blood glucose value  $G(t_d)$  comprises the steps of measuring a blood sample of the patient with said glucose meter and producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

98. The method of Claim 90, wherein said insulin dose has an insulin type, said method further comprises the steps of entering said insulin type in said processor, and wherein said insulin action value  $F_k(t_d)$  is determined in dependence upon said insulin type.

99. The method of Claim 98, wherein said insulin type is selected from the group consisting of regular insulin and lispro insulin.

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100. The method of claim 90, further comprising the steps of entering in said processor a plurality of blood glucose values and a plurality of insulin dose values, determining from said glucose values and said insulin dose values an adjusted insulin dose values an adjusted insulin sensitivity value, and storing said adjusted insulin sensitivity value in said memory.

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